

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NORTH CAROLINA  
ASHEVILLE DIVISION  
1:20-cv-242-MOC-WCM**

**DONNA S. SHOOK, as Executrix of the** )  
**Estate of Jean S. Satterfield, aka Jean S.** )  
**Penland,** )

**Plaintiff,** )

**vs.** )

**BOSTON SCIENTIFIC CORP.,** )

**Defendant.** )

---

**ORDER**

**THIS MATTER** comes before the Court on a Motion to Dismiss filed by Defendant, (Doc. No. 12), in which Defendant asks this Court to dismiss Plaintiff's Amended Complaint. The Court held a hearing on the motion to dismiss on March 9, 2021.

**I. BACKGROUND**

Plaintiff's Amended Complaint arises out of the death of Jean S. Penland on July 29, 2015, from injuries she received when a Watchman™ left atrial appendage closure device, hereafter "Watchman™" or "Watchman™ device," designed and manufactured by Defendant Boston Scientific Corporation, malfunctioned upon attempted implantation. In the Amended Complaint, Plaintiff asserts state-law claims seeking relief for Defendant's negligence in the manufacture and assembly of the particular Watchman™ device used during Ms. Penland's procedure, and breach of the implied warranty per N.C. Gen. Stat. § 25-2-315, that this particular device was fit for its intended and particular purpose. See (Plaintiff's Amended Compl., ¶¶ 43-61).

The Watchman™ is designed and intended to be permanently implanted in a patient's

heart to seal off the left atrial appendage. (Id. ¶ 13). Boston Scientific filed for premarket approval (hereinafter “PMA”) as required by the Food and Drug Administration (hereinafter “FDA”) on March 14, 2013. The PMA application contained, among other things, a required complete description of the device, including a description of the functional components of the device, the significant physical and performance characteristics of the device, and the principles of operation of the device. (Id. ¶ 15). Within its PMA application, Boston Scientific described the Watchman™ as a device that during implantation would be subject to the cardiologist’s control and would not release from the core wire until positioning was confirmed and the deployment knob was intentionally turned counterclockwise sufficiently to unscrew the core wire from the threaded insert on the device. (Id. ¶ 19).

On March 13, 2015, the FDA approved Boston Scientific’s premarket approval application for the Watchman™ based, in part, on these specific performance characteristics and principles of operation. (Id. ¶ 20). During Ms. Penland’s February 15, 2018, surgical procedure, immediately upon unsheathing the Watchman™ and prior to the cardiologist turning the deployment knob, the device embolized free of the core wire and could be seen moving about the left atrium until it lodged in the mitral valve with the device’s barbs caught in the subvalvular apparatus. (Id. ¶ 28).

Subsequent to the device’s malfunction, Ms. Penland underwent an emergent operation to retrieve the device, which included 77 minutes of cardiopulmonary bypass. Ms. Penland’s injuries worsened over the coming months as she struggled with severe respiratory distress. On July 30, 2018, Ms. Penland died from hypoxemic respiratory failure secondary to diastolic heart failure. (Id. ¶¶ 28-41). Ms. Penland’s daughter Donna Shook then filed this action, as executrix of Ms. Penland’s estate.

## **II. STANDARD OF REVIEW**

Federal Rule of Civil Procedure 12(b)(6) provides that a motion may be dismissed for failure to state a claim upon which relief can be granted. A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of the complaint without resolving contests of fact or the merits of a claim. Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992), cert. denied, 510 U.S. 828 (1993). Thus, the Rule 12(b)(6) inquiry is limited to determining if the allegations constitute “a short and plain statement of the claim showing the pleader is entitled to relief” pursuant to Federal Rule of Civil Procedure 8(a)(2). To survive a defendant’s motion to dismiss, factual allegations in the complaint must be sufficient to “raise a right to relief above a speculative level.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Thus, a complaint will survive if it contains “enough facts to state a claim to relief that is plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570).

For the purposes of a Rule 12(b)(6) analysis, a claim has facial plausibility “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. (quoting Twombly, 550 U.S. at 556). The Court must draw all reasonable factual inferences in favor of the plaintiff. Priority Auto Grp., Inc. v. Ford Motor Co., 757 F.3d 137, 139 (4th Cir. 2014). In a Rule 12(b)(6) analysis, the Court must separate facts from legal conclusions, as mere conclusions are not entitled to a presumption of truth. Iqbal, 556 U.S. at 678. Importantly, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. However, well-pleaded factual allegations are entitled to a presumption of truth, and the court should determine whether the allegations plausibly give rise to an entitlement to relief. Id. at 679.

## **III. DISCUSSION**

Class III medical devices, such as the Watchman™ device, are subject to the FDA's intensive PMA process. In reviewing PMA applications, the FDA must “weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” 21 U.S.C. § 360c(a)(2)(C). After completing its review, the FDA may grant or deny approval. See 21 U.S.C. § 360e(d). If the FDA grants premarket approval to a medical device, a manufacturer may not make changes to the design, manufacturing process, or labeling of that device without first securing permission from the FDA.

The Watchman™ device was approved through the PMA process, and multiple supplemental premarket approvals for the Watchman™ device were also granted by the FDA in subsequent years. See Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications, 80 Fed. Reg. 54,488-01 (Sept. 29, 2015) (listing the original PMA for the Watchman™ device). The original and supplemental premarket approvals remain in effect and have never been suspended or revoked.

By passing the Medical Device Amendments of 1976, Congress ceded exclusive regulatory authority over medical devices to the FDA because it determined that satisfaction of the agency's PMA requirements is adequate, as a matter of law, to safeguard the public in its use of medical devices. Congress further expressly preempted certain state-law statutory or common-law claims that relate “to the safety or effectiveness of the device or to any other matter included in” a federal requirement. 21 U.S.C. § 360k(a)(2). With respect to Class III medical devices, like the Watchman™ device, the Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008), established a two-step procedure for determining if state-law claims are preempted by the MDA. First, the court must determine whether “the federal government has established requirements applicable to” the particular medical device. Riegel, 552 U.S. at 321.

Class III medical devices that have received premarket approval—like the Watchman™ device—automatically satisfy this first condition. See id. at 322 (holding that premarket approval imposes federal “requirements” under the MDA). Second, the court must determine whether the plaintiff’s state-law causes of action would impose requirements “different from, or in addition to” those established by the FDA. Id. at 323 (quoting § 360k(a) and noting that requirements must relate to “the safety or effectiveness of the device” or “any other matter included in a requirement applicable to the device under” the MDA).

The Riegel Court recognized a narrow exception to express preemption by holding that “[s]tate requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.” 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a) (emphasis added)). Furthermore, the Court held that “[section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” Id. (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)).

Defendant contends that Plaintiff’s claims should be dismissed because they are expressly preempted by Section 360k. Defendant argues that Plaintiff’s state law claims seek to impose additional or different requirements on a medical device that received premarket approval from the FDA. Defendant further contends Plaintiff’s claims should be dismissed because her amended complaint “has not satisfied the exacting standard necessary to plead a parallel claim.” (Def. Memorandum, p. 2). Defendant asserts “the allegation that a Watchman™ device disconnected from its core wire during a surgery does not plausibly show that [Boston Scientific Corporation] violated the [Food, Drug, and Cosmetic Act] in manufacturing that device, but rather is merely speculative.” (Id.).

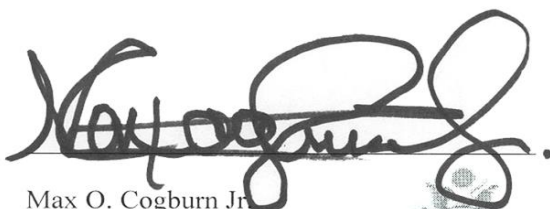
In response, Plaintiff asserts that her claims arise out of a clear and specific manufacturing and assembly defect, and simply seek to hold the Defendant's medical device to the performance characteristics and functional principles presented to and approved by the FDA. Plaintiff has alleged that because of a manufacturing and assembly defect, the particular Watchman<sup>TM</sup> device used in Ms. Penland's case did not perform as designed and intended, as approved by the FDA, and in compliance with its FDA premarket approval. Thus, Plaintiff asserts that her claims rest within the exception provided in Riegel and therefore are not expressly preempted. Plaintiff further contends that Defendant has too narrowly construed the pleading standard upon which Plaintiff's claims will be evaluated, and either overlooks, or simply ignores, the specificity with which Plaintiff details the manufacturing and assembly defect which constitutes Defendant's violation of federal regulations.

As noted, the Court held a hearing on the motion to dismiss on March 9, 2021. The Court has determined that, in light of the lenient pleading standards of Iqbal and Twombly, the Court will deny the motion to dismiss and allow the parties to proceed with discovery. In so holding, the Court makes no determination on federal preemption at this time. Rather, the Court has determined that Plaintiff has merely sufficiently pleaded enough facts to overcome a motion to dismiss as to the preemption issue.

**IT IS THEREFORE ORDERED** that:

(1) Defendant's Motion to Dismiss, (Doc. No. 12), is **DENIED**.

Signed: March 22, 2021



Max O. Cogburn Jr.  
United States District Judge